

REMARKS

In the Office action dated December 4, 2003, claims 1-10 were considered and rejected.

Claims 2 and 3 are canceled without prejudice, and claims 1 and 4-10 are amended and presented for reconsideration. Applicants respectfully submit that no new matter is introduced by the present Amendment. Support for amendments to claim 1 may be found at least at page 7, lines 10-15 and claim 3 as originally filed. Amendments are made to claims 4-10 to correct typographical errors.

Drawings

The Office action requires Applicants to furnish a drawing under 37 CFR 1.81. However, the Office action does not indicate the specific subject matter towards which the drawing should be directed. Applicants will file appropriate drawing(s) after allowable claims have been indicated.

Claim Rejections Under 35 U.S.C. § 112

The Office action rejects claims 1-10 under 35 U.S.C. § 112, first paragraph. Without acquiescing, but in the interest of advancing prosecution, Applicants hereby amend claim 1. Applicants respectfully request reconsideration and withdrawal of these rejections.

Claim Rejections Under 35 U.S.C. § 102

The Office action rejects claims 1, 4, and 5 under 35 U.S.C. § 102(b) over PCT publication WO 99/37216 by Gellman *et al.* (hereinafter "Gellman"). The Office action rejects claims 1 and 2 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,961,528 to Birk *et al.* (hereinafter "Birk"). The Office action rejects claims 1 and 3 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,045,553 to Iverson *et al.* (hereinafter "Iverson"). The Office action rejects claims 1, 2, 4-7, and 9 under 35 U.S.C. § 102(b) over U.S. Patent No. 6,048,050 to Draenert (hereinafter "Draenert"). The Office action also rejects claim 1 and 3-5 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,997,541 to Schenk (hereinafter "Schenk").

Applicants respectfully traverse the § 102 rejections to the extent that they are maintained over amended independent claim 1 and claims depending therefrom.

Amended claim 1 recites a medical device comprising a push-in bone anchor and a protective cover. The cover comprises a brittle mass of biocompatible material. The push-in bone anchor is substantially encapsulated in the mass, and the cover breaks when the anchor is implanted into bone.

Gellman fails to teach or suggest all the elements of amended claim 1. Gellman fails to teach or suggest at least a protective cover comprising a brittle mass of biocompatible material or that such a cover breaks when the bone anchor is implanted into bone. Instead, Gellman describes covering a bone anchor with a balloon or a gelatin structure 890. See Gellman, page 3, lines 1-10; page 37, lines 17-22; and FIG. 43.

Birk also fails to teach or suggest all the elements of amended claim 1. According to Birk, part 46 in FIG. 3 is an insulator while part 44, shown in the same figure, is the tip of a skull pin which is needed for penetrating into a bone structure. See Birk, column 4, lines 52-65 and FIG. 3. Therefore, the blunt-ended insulator 46 cannot function as a bone anchor. Further, to the extent that the part 44 may function as a bone anchor, there is no protective cover taught or suggested in Birk. Birk fails to teach or suggest at least a protective cover, that the cover comprises a brittle mass of biocompatible material (column 5, line 13: "not brittle"), or that the cover breaks when the anchor is implanted into bone.

Iverson fails to teach or suggest all the elements of amended claim 1. First, Iverson describes a screw pin 10 which includes "a threaded portion 24" and not a push-in anchor as recited in amended claim 1. Iverson, column 3, lines 38-45; and FIG. 2.

Second, Iverson fails to teach or suggest that the protective cover breaks when the bone anchor is implanted into bone. In reference to a nonconductive layer 29, Iverson states that it is "bonded to at least the head portion 15 of the hybrid skull screw pin 10..." Iverson, column 4, lines 2-5. The verb "bond" is defined as "to cause to adhere firmly," in Webster's Ninth New Collegiate Dictionary, and as "to join securely, as with glue or

cement,” at www.dictionary.com.¹ Accordingly, the ceramic coating 29 in Iverson is not described as breaking upon implantation, but instead as remaining secured or adhered to the bone anchor. Further, the layer 29 is designed to function as an insulative layer to reduce heat conducted to a patient’s skin, and therefore meant to maintain its structural integrity *after* the implantation. See Iverson, column 2, lines 17-29; and column 4, lines 9-11. Therefore, Iverson does not teach or suggest that the layer should break after implantation of the bone anchor.

Draenert also fails to teach or suggest all the elements of amended claim 1. First, Draenert does not teach or suggest a push-in bone anchor as recited in amended claim 1. Instead, Draenert describes a dowel-shaped implant 10 for a bone screw to screw into. See Draenert, column 2, lines 53-63. Both the bone screw and the implant have a thread or a thread-like structure. See Draenert, column 7, lines 45-49; and FIG. 1. Second, Draenert fails to teach or suggest a protective cover comprising a brittle mass of biocompatible material or that the cover breaks when the bone anchor is implanted into bone. Instead, the implant 10 in Draenert “either spreads out when a screw is screwed in, or expands, or swells ... when it comes into contact with the body fluids in the bone, or it is screwed in itself.” Draenert, column 2, lines 58-63; and column 5, lines 49-60.

Schenk also fails to teach or suggest all of the elements of Applicants’ claim 1. First, Schenk fails to teach or suggest a push-in bone anchor. Instead, Schenk describes a bone screw 60 with a thread 61. See Schenk, column 5, lines 5-61; and FIG. 4. The washer 1 also has an external thread 9. See Schenk, column 3, lines 48-67; and FIGS. 1, 2, and 7. Second, Schenk does not teach or suggest substantially encapsulating the bone anchor. In contrast, the washer 1 in Schenk leaves a substantial portion of the bone screw 60 uncovered. See Schenk, FIGS. 4, 7, and 8. Third, Schenk does not teach or suggest that the cover breaks when the anchor is implanted into bone. See id. At least for the above reasons, Applicants respectfully request that all the 35 U.S.C. § 102(b) rejections of claim 1 and its dependent claims be reconsidered and withdrawn.

¹ A copy of relevant pages of the Webster’s Ninth New Collegiate Dictionary and a printout of the relevant pages at www.dictionary.com are attached as Exhibit A.

Claim Rejections Under 35 U.S.C. § 103

The Office action rejects claims 2 and 3 under 35 U.S.C. § 103(a) over Gellman in view of U.S. Patent No. 3,758,690 to Gittos *et al.* (hereinafter "Gittos"). The Office action further rejects claims 6-9 under 35 U.S.C. § 103(a) over Gellman.

Claims 2 and 3 are canceled. Gittos describes pharmacological properties in N-cyclopropyl-1-aminoindanes. Gittos does not cure Gellman's deficiencies with regard to Applicants' amended claim 1. Claims 6-9 depend from claim 1, and because amended claim 1 is submitted to be patentable over Gellman, so are claims 6-9. Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. § 103(a).

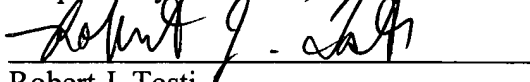
CONCLUSION

Applicants respectfully request entry of this amendment and response, withdrawal of all bases of rejection, and allowance of claims 1 and 4-10 in due course for at least the reasons presented above. The Examiner is invited to telephone Applicants' under signed representative at (617) 248-7374 to discuss any outstanding issues.

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bolero \bə-ˈleɪ(ə)-r(ə)-/ *n.* *pl.* -ros [Sp] (1787) 1: a Spanish dance characterized by sharp turns, stamping of the feet, and sudden pauses in a position with one arm arched over the head; also: music in 3/4 time for or suitable for a bolero 2: a loose waist-length jacket open at the front

bole-tus \bə-ˈlēt-əs/ *n.* *pl.* -tus-es or -ti \-tēt-ē/ [NL, genus name, fr. L, a fungus, fr. Gk *bolitēs*] (1601): any of a genus (*Boletus*) of soft pore fungi some of which are poisonous and others edible

bolivar \bə-ˈlī-vər, -bäl-ə-vär/ *n.* *pl.* -vares \bäl-ə-vär-əs, -bō-lī-/ or -vars [AmerSp *bolívar*, fr. *Simón Bolívar*] (ca. 1885) — see **MONEY** table

boliviano \bə-ˈlīv-ē-ān-ē-/ *n.* *pl.* -nos [Sp] (ca. 1872): a former monetary unit of Bolivia replaced in 1963 by the peso

boll \bōl/ *n.* [ME] (15c): the pod or capsule of a plant (as cotton)

bol-lard \bäl-ərd, *Brit* also -ärd/ *n.* [perh. irreg. fr. *bole*] (ca. 1795) 1: a post of metal or wood on a wharf around which to fasten mooring lines 2: BITT 1 3 chiefly *Brit*: any of a series of short posts set at intervals to delimit an area (as a traffic island) or to exclude vehicular traffic

bollix \bäl-iks/ *vt* [alter. of *ballocks*, *pl.* of *ballock* (testis), fr. ME, fr. OE *bealluc* — more at **BALL**] (1937): to throw into disorder; also: BUNGLE — *usu.* used with *up* — **bollix** *n.*

boll weevil *n.* (1895): a grayish weevil (*Anthonomus grandis*) about 1/4 inch long that infests the cotton plant and feeds on the squares and bolls both as a larva and an adult

boll-worm \bōl-worm/ *n.* (1847): CORN EARWORM; also: any of several other moths or their immature stages which feed on cotton bolls as larvae

bolo \bō-/ *n.* *pl.* bolos [Sp] (ca. 1899): a long heavy single-edged knife of Philippine origin

bolo-gna \bə-ˈlō-nē also -n(y)ə/ *n.* [short for *Bologna sausage*, fr. *Bologna*, Italy] (1596): a large smoked sausage of beef, veal, and pork

bolometer \bə-ˈlō-mē-tər/ *n.* [Gk *bolē* stroke, beam of light (fr. *ballein* to throw) + *E* -ō- + *-meter*] (1881): a very sensitive thermometer whose electrical resistance varies with temperature and which is used in the detection and measurement of feeble thermal radiation and is esp. adapted to the study of infrared spectra — **bolometer** \bō-lō-mē-ˈtrik/ *adj.* — **bolometerically** \-trī-k(ə)-lē/ *adv.*

boloney \bə-ˈlō-nē/ *var* of **BALONEY**

bol-tie \bō-lō- or bō-lä-tie/ *n.* [prob. fr. *bola*] (1964): a cord fastened around the neck with an ornamental clasp and worn as a necktie

Bolshevik \bōl-shə-vik, -bōl-, -bäl-, -vək/ *n.* *pl.* Bolsheviks also **Bolshevik** \bōl-shə-vik-ē, -bōl-, -bäl-, -və-kē/ [Russ *bol'shevik*, fr. *bol'she* larger] (1917) 1: a member of the extremist wing of the Russian Social Democratic party that seized supreme power in Russia by the Revolution of November 1917 2: COMMUNIST 3 — **Bolshevik** *adj.*

bolshevism \bōl-shə-viz-əm, -bōl-, -bäl-/ *n.* often *cap* (1917) 1: the doctrine or program of the Bolsheviks advocating violent overthrow of capitalism 2: Russian communism

Bolshevist \-vəst/ *n.* or *adj.* (1917): **BOLSHEVIK**

bolshevize \-vīz/ *vt.* -vīz-; -vīz-ing (1919): to make Bolshevik — **Bolshevization** \bōl-shə-və-zā-shən, -bōl-, -bäl-/ *n.*

bolshie or **bolshy** \bōl-shē, -bōl-, -bäl-/ *n.* or *adj.* often *cap* (1918): **BOLSHEVIK**

bolster \bōl-stər/ *n.* [ME, fr. OE; akin to OE *belg* bag — more at **BELLY**] (bef. 12c) 1: a long pillow or cushion 2: a structural part designed to eliminate friction or provide support or bearing; esp.: the horizontal connection between the volutes of an Ionic capital

bolster *vt.* **bolstered**; **bolstering** \-st(ə)-rɪŋ/ (1508) 1: to support with or as if with a bolster: **REINFORCE** 2: to give a boost to (news that ~ed his spirits) — **bolsterer** \-stər-ər/ *n.*

bolt \bōlt/ *n.* [ME, fr. OE; akin to OHG *bolz* crossbow bolt, Lith *beldėti* to beat] (bef. 12c) 1: a shaft or missile designed to be shot from a crossbow or catapult; esp.: a short stout usu. blunt-headed arrow 2: a lightning stroke: **THUNDERBOLT** 3: a wood or metal bar or rod used to fasten a door 4: the part of a lock that is shot or withdrawn by the key 5: a roll of cloth of specified length 6: a roll of wallpaper of specified length 7: a metal rod or pin for fastening objects together that usu. has a head at one end and a screw thread at the other and is secured by a nut 8: a block of timber to be sawed or cut 9: a short round section of a log 10: a metal cylinder that drives the cartridge into the chamber of a firearm, locks the breech, and usu. contains the firing pin and extractor

bolt *vt.* (13c) 1: to move suddenly or nervously: **START** 2: to move rapidly: **DASH** 3: to dart off or away: **FLEE** 4: to break away from control or a set course 5: to break away from or oppose one's political party or candidate ~ *vt.* 1: *archaic*: **SHOOT, DISCHARGE** 2: **FLUSH, START** (~ rabbits) 2: to say impulsively: **BLURT** 3: to secure with a bolt 4: to attach or fasten with bolts 5: to swallow hastily or without chewing 6: to break away from or refuse to support (as a political party)

bolt *adv.* (14c) 1: in an erect or straight-backed position: **RIGIDLY** (sat ~ upright) 2: *archaic*: **DIRECTLY, STRAIGHT**

bolt *n.* (1550): the act or an instance of bolting

bolt *vt.* [ME *bullen*, fr. OF *buleter*, of Gmc origin; akin to MHG *biuteln* to sift, fr. *biutel* bag, fr. OHG *bütill*] (13c) 1: to sift (as flour) usu. through fine-meshed cloth 2: *archaic*: **SIFT**

bolt-action \bōl-tak-shən/ *adj.* of a firearm (1896): loaded by means of a manually operated bolt

bolter \bōl-tər/ *n.* (15c): a machine for bolting flour; also: the operator of such a machine

bolter *n.* (ca. 1699): one that bolts: as: a: as horse given to running away 4: a voter who breaks away from or opposes his party

bolterope \bōl-rōp/ *n.* (ca. 1626): a strong rope stitched to the edges of a sail to strengthen it

bolus \bō-ləs/ *n.* [LL, fr. Gk *bōlos* lump; akin to L *bulbus* bulb] (1562): a rounded mass: as: a: a large pill 4: a soft mass of chewed food

bomb \bām/ *n.* [F *bombe*, fr. It *bomba*, prob. fr. L *bombus* deep hollow sound, fr. Gk *bombos*, of imit. origin] (1684) 1: an explosive device fused to detonate under specified conditions 2: **ATOM BOMB**; also: nuclear weapons in general — *usu.* used with *the* 2: a vessel for compressed gases: as: a: a pressure vessel for conducting chemical experiments 4: a small dispenser for a substance (as paint or an insecticide) stored under pressure 3: a rounded mass of lava exploded

from a volcano 4: a lead-lined container for radioactive material

FAILURE, FLOP (the play was a ~) 6 *Brit*: a large sum of money

Brit: a great success: **HIT** 8: a long pass in football

bomb *vt.* (1688) 1: to attack with or as if with bombs: **BOMBARD**: to defeat decisively ~ *vi.* 1: to fall flat: **FAIL** 2 slang: to move rapidly (~ed down the hill) — **bombing** *n.*

bombard \bām-bārd/ *n.* [ME *bombarde*, fr. MF, prob. fr. L *bombus*] (15c): a late medieval cannon used to hurl large stones

bombard \bām-bārd/ *also* bām-/ *vt.* (1686) 1: to attack esp. with artillery or bombers 2: to assail vigorously or persistently (as with questions) 3: to subject to the impact of rapidly moving particles (electrons or alpha rays) *syn* see **ATTACK** — **bombardment** \-mənt/ *n.*

bombardier \bām-bō-ri-ä-/ *n.* (1560) 1: *archaic*: **ARTILLERMAN** 2: a noncommissioned officer in the British artillery

bomber *n.* *b*: a member who uses the bombsight and releases the bombs

bombard \bām-bōrd, -dōn, -bām-bārd-/ *n.* [F, fr. It *bombarda*] (1856) 1: the bass member of the shawm family 2: a bass tuba

bombast \bām-bast/ *n.* [ME *bombast* cotton padding, fr. MF *bombac*, fr. ML *bombac*, *bombax* cotton, alter. of L *bombyx*, *bombyx* silkworm, silk, fr. Gk *bombyk*, *bombyx*] (1589): pretentious inflated speech or writing

bombastic \bām-bas-tik/ *adj.* (1704): marked by or given to bombast

POMPOUS, OVERBLOWN — **bombastically** \-tī-k(ə)-lē/ *adv.*

bombazine \bām-bō-zēn/ *n.* [MF *bombasin*, fr. ML *bombacinum*, *bombycinum* silken texture, fr. L, neut. of *bombycinus* of silk, fr. *bombyx*, *bombyx*] (1572) 1: a twilled fabric with silk warp and worsted filling 2: a silk fabric in twill weave dyed black

bombe \bām, -bō(m)-/ *n.* [F, lit., bomb] (1892): a frozen dessert containing ice cream and formed in layers in a round or cone-shaped mold

bombed \bāmd/ *adj.* (1969): affected by alcohol or drugs: **DRUNK**

HIGH

bomber \bām-ər/ *n.* (1915): one that bombs; *specif*: an airplane designed for bombing

bombinate \bām-bō-nāt/ *vi.* -nat-ed; -nat-ing [NL *bombinatus*, pp. of *bombinare*, alter. of L *bombilare*, fr. *bombyx*] (1880): **BUZZ, DRONE**

bombinate \bām-bō-nāt/ *n.* [NL *bombinatus*, pp. of *bombinare*, alter. of L *bombilare*, fr. *bombyx*] (1880): **BUZZ, DRONE**

bombproof \bām-prūf/ *adj.* (1702): safe from the force of bombs

bombshell \bām-shel/ *n.* (1708) 1: **BOMB** 2: one that is stunning, amazing, or devastating (the book was a political ~)

bomb-sight \-sīt/ *n.* (1917): a sighting device for aiming bombs

bona fide \bō-nā-fīd, -bān-, -bō-nā-fīd-ē, -fīd-ē/ *adj.* [L, lit., in good faith] (1788) 1: made in good faith without fraud or deceit (a bona fide offer to buy a farm) 2: made with earnest intent: **SINCERE**; neither specious nor counterfeit: **GENUINE** *syn* see **AUTHENTIC**

bona fides \bō-nā-fīd-ēz/ *n.* [L, lit., good faith] (1798): lack of fraud or deceit: **SINCERITY** (a man on whom suspicion had never rested and whose bona fides was unshakable — Victor Canning)

bonanza \bō-nān-zə/ *n.* [Sp, lit., fair weather, fr. ML *bonacia*, alter. (influenced by L *bonus* good) of L *malacia* calm at sea, fr. Gk *malakia* lit., softness, fr. *malakos* soft] (1842) 1: an exceptionally large and rich ore shoot or pocket in veins carrying gold and silver 2: a something that is very valuable, profitable, or rewarding (a box-office ~) 3: an extremely large amount (expected a ~ of sympathy)

Bona-partism \bō-nā-pārt-iz-əm/ *n.* (1815) 1: support of the French emperors Napoleon I, Napoleon III, or their dynasty 2: a political movement associated chiefly with authoritarian rule usu. by a military leader ostensibly supported by a popular mandate — **Bona-partist** \-pārt-ist/ *n.* or *adj.*

bon-bon \bān-bān/ *n.* [F, (baby talk), redupl. of *bon* good, fr. L *bonus* — more at **BOUNTY**] (1796): a candy with chocolate or fondant coating and fondant center that sometimes contains fruits and nuts

bond \bānd/ *n.* [ME *band*, *bond* — more at **BAND**] (12c) 1: something that binds or restrains: **FETTER** 2: a binding agreement: **COVENANT** 3: a: a band or cord used to tie something 4: a material or device for binding 5: an attractive force that holds together the atoms, ions, or groups of atoms in a molecule or crystal — *usu.* represented in formulas by a line or dot 6: an adhesive, cementing material, or fusible ingredient that combines, unites, or strengthens 7: a uniting or binding element or force: **TIE** (the ~s of friendship) 8: an obligation made binding by a money forfeit; also: the amount of the money guarantee 9: one who acts as bail or surety 10: an interest-bearing certificate of public or private indebtedness (a 20-year ~ issue to finance a new courthouse) 11: an insurance agreement pledging surety for financial loss caused to another by the act or default of a third person or by some contingency over which the third person may have no control 12: the systematic lapping of brick in a wall 13: the state of goods made, stored, or transported under the care of bonded agencies until the duties or taxes on them are paid 14: a 100-proof straight whiskey aged at least four years under government supervision before being bottled — called also *bonded whiskey*

bond *vt.* (1677) 1: to lap (as brick) for solidity of construction 2: to secure payment of duties and taxes on (goods) by giving a bond 3: to convert into a debt secured by bonds 4: to provide a bond for or cause to provide such a bond (~ an employee) 5: to cause to adhere firmly 6: to embed in a matrix 7: to hold together in a molecule or crystal by chemical bonds ~ *vi.* to hold together or solidify by or as if by means of a bond or binder: **COHERE** — **bondable** \bān-də-bəl/ *adj.* — **bond-er** *n.*

bond *adj.* [ME *bonde*, fr. *bonde* peasant, serf, fr. OE *bōnda* household, fr. ON *bōndi*] *archaic* (14c): bound in slavery

bondage \bān-dij/ *n.* (14c) 1: the tenure or service of a vassal, serf, or slave 2: a state of being bound usu. by compulsion (as of law or mastery): as: a: **CAPTIVITY, SERFDOM** (the ~ of the Israelites in Egypt) 4: servitude or subjugation to a controlling person or force (young people in ~ to drugs)

bonded \bānd-əd/ *adj.* (1945): composed of two or more layers of the same or different fabrics held together by an adhesive (~ jersey)

bondholder \bānd-hōl-dər/ *n.* (1823): one that holds a government or corporation bond

bonding \bānd-ɪŋ/ *n.* (1976): the formation of a close personal relationship (as between a mother and child) esp. through frequent or constant association



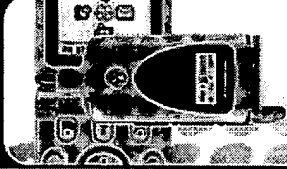
bond

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Bond   **Pronunciation Key** (bɔ̃nd), **Julian**. Born 1940.

American politician and civil rights leader who was elected to the Georgia legislature (1966) but temporarily barred from taking office because of his opposition to the Vietnam War.

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bond   **Pronunciation Key** (bɔ̃nd)
n.

1. Something, such as a fetter, cord, or band, that binds, ties, or fastens things together.
2. Confinement in prison; captivity. Often used in the plural.
3. A uniting force or tie; a link: *the familial bond*.
4. A binding agreement; a covenant.
5. A duty, promise, or other obligation by which one is bound.
6.
 - a. A substance or agent that causes two or more objects or parts to cohere.
 - b. The union or cohesion brought about by such a

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substance or agent.

7. A chemical bond.
8. A systematically overlapping or alternating arrangement of bricks or stones in a wall, designed to increase strength and stability.
9. Law.
 - a. A written and sealed obligation, especially one requiring payment of a stipulated amount of money on or before a given day.
 - b. A sum of money paid as bail or surety.
 - c. A bail bondsman.
10. A certificate of debt issued by a government or corporation guaranteeing payment of the original investment plus interest by a specified future date.
11. The condition of taxable goods being stored in a warehouse until the taxes or duties owed on them are paid.
12. An insurance contract in which an agency guarantees payment to an employer in the event of unforeseen financial loss through the actions of an employee.
13. Bond paper.

v. bond·ed, bond·ing, bonds

v. tr.

1. To mortgage or place a guaranteed bond on.
2. To furnish bond or surety for.
3. To place (an employee, for example) under bond or guarantee.
4. To join securely, as with glue or cement.
5. To join (two or more individuals) in or as if in a nurturing relationship: "What bonded [the two men]—who spoke rarely and have little personal rapport—was patience and a conviction that uncontrolled inflation endangers... society" (Robert J. Samuelson).
6. To lay (bricks or stones) in an overlapping or alternating pattern.

v. intr.

1. To cohere with or as if with a bond.
2. To form a close personal relationship.

[Middle English, variant of *band*, from Old Norse. See *bhendh-* in Indo-European Roots.]

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